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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/201,228	11/30/98	GRIFFA18	R 9710-004

HM22/0518

PENNIE & EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

EXAMINER	
MARSCHEL, A	
ART UNIT	**PAPER NUMBER**
1631	#6

DATE MAILED: 5/18/00

Response to Res. Req: 5/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

REFERRED TO Ueda
RECEIVED PEDC
MAY 23 2000
O.K. for filing

REFERRED TO Walker
REC'D Chheda
MAY 22 2000
Pennie & Edmonds
O.K. for filing

PTO-90C (Rev. 2/95)

2 - Mail Copy

Office Action Summary

Application No.	Applicant(s)
09/201,228	Griffais t al.
Examiner	**Group Art Unit**
Ardin Marschel	1631

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-56 is/are pending in the applicat

Of the above claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-56 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152 .

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-16, 30, 51, and 52; drawn to polynucleotides and compositions containing same, classified in Class 536, subclass 23.1; and Class 435, subclasses 243, 320.1, and 325. If this group is elected, then the below sequence election requirement also is required.

II. Claims 17 and 18, drawn to methods of expression of polypeptides from polynucleotides, classified in Class 435, subclass 69.1. If this group is elected then the below sequence election requirement also is required.

III. Claims 19-23 and 31, drawn to polypeptides, classified in Class 530, subclass 350. If this group is elected then the below sequence election requirement also is required.

IV. Claims 24, 25, 55, and 56; drawn to an antibody, classified in Class 530, subclass 387.1. If this group is elected then the below sequence election requirement also is required.

V. Claims 26, 27, 48, 53, and 54; drawn to compositions and methods of detection based on polynucleotide hybridization, classified in Class 435, subclass 6. If this group is elected then the below sequence election requirement also is required.

VI. Claim 28, drawn to methods of screening based on an antibody reagent usage, classified in Class 435, subclass 7.1. If this group is elected then the below sequence election requirement also is required.

VII. Claims 29, 49, and 50; drawn to methods of detection based on a polypeptide reagent usage, classified in Class 435, subclass 7.1. If this group is elected then the below sequence election requirement also is required.

VIII. Claims 32-43, drawn to immunogenic polypeptides and methods of administration of them, classified in Classes 424 and 514, subclasses 184.1 and 2, respectively. If this group is elected then the below sequence election requirement also is required.

IX. Claims 44-47, drawn to immunogenic DNAs, classified in Class 514, subclass 44. If this group is elected then the below sequence election requirement also is required.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect up to 10 nucleic acid

sequences (See MPEP 803.04).

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. And permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally 10 sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be

independent and distinct inventions and will continue to be examined together.

Examination will be restricted to only the elected sequences.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups (I, II, V, and IX); Groups (III, VII, and VIII); and Groups (IV and VI) are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups III, VII, and VIII the critical feature is a polypeptide; for Groups I, II, V, and IX the critical feature is nucleic acids; and for Groups IV and VI the critical feature is an antibody. It is acknowledged that various processing steps may cause a polypeptide of Groups III, VII, or VIII to be directed as to its synthesis by a polynucleotide of Groups I, II, V, or IX; however, the completely separate chemical types of the inventions of the nucleic acid, polypeptide, and antibody Groups supports the undue search burden if both were examined together. Additionally, polynucleotides, polypeptides, and antibodies have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct

because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three Groupings of (I, II, V, and IX); (III, VII, and VIII); and (IV and VI; are independent and/or distinct invention types for restriction purposes.

The inventions of Group I and Groups II, V, and IX are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acids of Group I can be used in the distinct processes of the inventions of Groups II, V, and IX. One use is directed to polypeptide expression(II), another for hybridization assay(V), and the other is directed to compositions which immunize deemed to be a vaccine(IX). Alternatively, the nucleic acids of Group I can be used in antisense therapy which is also a clearly distinct usage of such nucleic acids.

The inventions of Group III and Groups VII and VIII are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2)

the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptides of Group III can be used in the distinct processes of the detection method inventions of Group VII and, alternatively, in vaccination processess of Group VIII. Alternatively, the polypeptides of Group II can be utilized in replacement therapy for a missing protein, or, the activity of a protein can be utilized in an industrial process for chemical processing.

The inventions of Group IV and Group VI are related as product and a distinct process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the antibodies of Group IV can be used in the distinct processes of the inventions of Groups VI, or, alternatively, in either antibody therapy or affinity purification methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be

examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 15, 2000

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER